UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,691	05/30/2006	Sergei A. Kazakov	367592000500	9752

25226 7590 05/15/2008
MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
ZARA, JANE J	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
05/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,691	KAZAKOV ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, 18 drawn to nucleic acids which circularize around a target nucleic acid in vitro, classifiable in class 536, subclass 24.5.

II. Claims 1-14, 16-18 drawn to nucleic acids which circularize around a target nucleic acid in vivo, classifiable in class 536, subclass 23.1.

III. Claims 19-21, drawn to methods of reducing efficiency of transcription or translation, classifiable in class 435, subclass 91.31.

IV. Claims 22-29, drawn to a method of detecting the presence or absence of a target nucleic acid molecule, classifiable in class 435, subclass 6.

V. Claim 30, drawn to library comprising a plurality of polynucleotides, classifiable in class 536, subclass 24.3.

VI. Claim 31, drawn to a method of selecting polynucleotides that are capable of topologically linking to a target nucleic acid molecule, classifiable in class 435, subclass 6.

VII. Claim 32, drawn to a kit comprising a polynucleotide that binds and circularizes a target nucleic acid molecule, classifiable in class 536, subclass 23.2.

VIII. Claim 33, drawn to a kit comprising a library comprising a plurality of polynucleotides, classifiable in class 536, subclass 24.33.

The inventions are distinct, each from the other because of the following reasons:

Inventions comprising the different nucleic acid molecules, kits and libraries of Groups I, II, V, VII and VIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The operation, function and effects of the different polynucleotides, libraries and kits are completely different from each other in composition, sequence and chemical structure. In the instant case, the inventions as claimed are chemically, biologically, functionally and structurally distinct and different (different polynucleotide and chemical structures, different sequences, different target sequences). One is not needed for the other and each can be used for a different purpose (e.g. as molecule weight markers in electrophoresis, as hybridization probes or for potential therapeutic agents to treat medical conditions).

Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions III, IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of these different Groups are unrelated as they comprise distinct steps and utilize different products, and produce different biological outcomes, which demonstrate that each method has a different mode of operation. The methodology and materials necessary for each of these distinct

methods differ significantly: method of reducing efficiency of transcription or translation (Group III); method of detecting the presence or absence of a target nucleic acid molecule (Group IV); method of selecting polynucleotides capable of topologically linking to target nucleic acid molecule (Group VI). Each method utilizes different and distinct nucleic acid molecules, different target nucleic acid sequences and different inhibitory molecules, which constitute chemically, biologically and functionally different and distinct molecules or chemical entities. Each method comprises distinct steps that are not present in the other methods, and measure different and distinct biological and biochemical outcomes. Therefore, each method is divergent in materials and steps. For these reasons the inventions of III, IV and VI are patentably distinct.

Inventions Groups I, II, V, VII, VIII and III, IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Groups I, II, V, VII, VIII can be used as hybridization probes, molecular weight markers or for as potential therapeutic candidates. In the instant case, the inventions as claimed comprise compositions and methods comprising chemically, biologically, structurally and functionally different and distinct compositions and methods steps. Each target region and nucleotide sequence is different and distinct from the other and one does not render the other obvious. Furthermore, the

inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The distinct steps and products require separate and distinct searches, each requiring a separate search for the steps and molecules involved in the various methods steps. The searches required for each of the methods and compositions claimed would not be coextensive with each other. Searching the inventions of Groups IVIII together would impose a serious search burden. In the instant case, the search of each of the polynucleotides, kits, libraries is not coextensive with the other, and a search of the methods of Groups III, IV and VI will not be coextensive with the search of the compositions of Groups I, II, V, VII and VIII. The inventions have a separate status in the art as shown by their different classifications. In cases such as this one, the different target sequences, probes and catalytic molecules are searched in appropriate databases. There is a search burden also in the non-patent literature. Similarly, there may have been classical genetics papers that had no knowledge of the screening or expression modulation approaches claimed, but spoke to the molecules for in vitro gene probing. Searching, therefore is not coextensive. For these reasons, it would be burdensome to search the inventions of Groups of I-VIII together, and including all of the nucleic acid molecules and compositions claimed.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance

with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
5-13-08

/Jane Zara/

Primary Examiner, Art Unit 1635